Request for Proposals

831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

Introduction Request for Proposals (RfP)

In a collaboration with 31 international partners, the EU/IMI project called Trials@Home (T@H) will check the feasibility of fully remote Clinical Trials (RDCTs). For the execution of these RDCTs, technologies are needed. Some of them are already familiar and/or contracted by the T@H partners, but other RDCT technologies are not and need to be introduced in this project and pilot study. We are looking for these technologies, and that's why this Request for Proposals has been launched.
All the technologies are categorized in Basic Building Blocks (BBB) categories based on key functionalities within those building blocks, which are called activities. The scope of this RfP contains the following BBB's / categories: Data Acquisition & Processing, Patient Engagement, Setup & Design, Closeout & Reporting, Operation & Coordination, and Recruit & Enroll. A description of these BBB's and required technologies can be found in the 'BBB profile' documents, also attached on the T@H website.

Submitting your proposal
We request you to create a proposal for the technologies that you are able to deliver. Please be very clear about the functionalities of your proposal: what part of the scope can be covered?
Also we would like to receive a total price, that shows at least the following components:

- Give a clear definition of the scope and detailed assumptions
- Present an overview with costs per line item (no lump sum)
- Per task indicate the estimated hours and role per task (including hourly rates)
- If applicable, detailed information about license costs per month/year/user etc
- Transparency when you outsource parts to third parties
- Overview of other costs and pass though costs.

You will be able to upload your proposal on the T@H website by clicking the 'Submit a proposal' button. After you have submitted a proposal for one or more of the requested technologies from the RfP, your proposal will be quickly checked on the knock-out criteria per relevant BBB. After a positive conclusion, you will receive a survey including instructions from T@H. We kindly request you to fill in this survey, including remarks and documentation / proof to strengthen your answers, and return this form ultimately within 2 weeks.

Assessment process & criteria
After submitting a proposal and returning a completed survey, per BBB these documents per vendor will be assessed. First a check will be done on the knock-out criteria that apply. Then, if passed, the formal assessment will start. Per BBB, an assessment committee is composed, that will score all proposals including a self-assement survey, based on pre-defined quality criteria and vendor characteristics. You will find these quality criteria per BBB in the document 'Quality criteria per BBB'.

The self-assessment will result in a ranking per BBB. Numbers 1, 2 and 3 of this ranking per BBB will be invited for a pitch & interview. Their offer will be discussed, and the assessment team is allowed to adjust their scores per vendor after this pitch and interview.
The vendor that ranks number 1 after the pitch and interview, and is assessed as fit for purpose, will be nominated as candidate technology for the pan-European pilot study.

Please note that, due to different unforeseeable circumstances, T@H always has the possibility not to award a contract.

FYI, upon award of services, the attached contract template will be completed and executed. The standard terms and conditions are non-negotiable.

Questions
All interested vendors may ask questions during this RfP. You can do so by sending your question per e-mail to: trialsathome@umcutrecht.nl
Questions will be collected and answers will be – open to everybody - uploaded on the Trials@Home website.

Planning

Possibility to ask questions (e-mail) and submit a proposal:	18 Dec 2020 – 15 Jan 2021
Webinar with further explanation of the project & RfP:	6 Jan 2021, 3 PM CET
Deadline for submitting a proposal:	15 Jan 2021
Deadline for returning self-assessment form:	29 Jan 2021
Assessment of proposals by T@H assessment teams:	15 Jan – 15 Feb 2021
Pitch + interviews:	16 Feb – 1 March 2021
Awarding contracts:	From 1 March 2021

Please note that this planning could be subject to change. If changes occur, this will be communicated with all relevant parties.

Info on scope of T@H pilot study (assumptions):

- Aim of the T@H pilot study: to compare RDCT and hybrid (i.e. partly remote) clinical trial approaches with the conventional site-based clinical trial approach regarding several key performance indicators
- Indication: type 2 diabetes
- IMP: insulins (all participants will receive the same IMP intervention)
- Mode of administration: self-injection pen
- Arms: 3 (conventional, hybrid, remote clinical trial approach)
- Research question, operational: performance comparison of 3 arms, e.g. regarding data quality and KPIs
- Research question, clinical: does switching of uncontrolled type 2 DM patients from their current basal insulin to IMP improve diabetes control differentially between the three arms?
- Sites: 10 for remote arm (1 per country); 50 for traditional/hybrid arms in total
- Countries/languages: 10 European
- Study population: sample size 1000; adult, non-vulnerable subjects >
- Anticipated start April (FPFV) 2022, expect phasing of 6 months treatment, 6 months with a recruitment period of 6 months